DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 16, 2014

Covidien, LLC
c/o Julie Underdahl
Senior Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441-2651

Re: K141801
Trade/Device Name: HawkOne Directional Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper Regulatory
Class: Class II
Product Code: MCW
Dated: September 15, 2014
Received: September 16, 2014

Dear Ms. Underdahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141801

Device Name
HawkOne Directional Atherectomy System

Indications for Use *(Describe)*
The HawkOne Directional Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

HawkOne™ Directional Atherectomy System

This 510(k) summary is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	Covidien llc 4600 Nathan Lane N Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Julie Underdahl Senior Regulatory Affairs Specialist
Date Prepared	July 2, 2014

2. Subject Device

Device Trade Name	HawkOne Directional Atherectomy System
Device Common Name	Catheter, Peripheral, Atherectomy
Classification Name	Intraluminal Artery Stripper 21 CFR 870.4875, Product Code MCW
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	TurboHawk™ Peripheral Plaque Excision System
510(k) Number	K111723
510(k) Clearance Date	October 27, 2011
Device Trade Name	TurboHawk™ Peripheral Plaque Excision System
510(k) Number	K103618
510(k) Clearance Date	January 5, 2011

4. Device Description

The HawkOne™ directional atherectomy system (HawkOne catheter and cutter driver) is designed for the treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries. When used in complex, hard, calcified lesions, the HawkOne catheter should be paired with the SpiderFX™ embolic protection device to mitigate risk of distal embolization that may be generated by the breakdown of heavily calcified plaque. The HawkOne catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the HawkOne catheter is a small cutting assembly comprised of a rotating inner

blade contained within a tubular housing. The proximal end of the HawkOne catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the cutter driver. The cutter driver (catalog number H1-14550) is a battery driven, internally powered device, designed to power the HawkOne directional atherectomy catheter. For information about the SpiderFX embolic protection device, reference the Instructions for Use provided with the device.

The HawkOne directional atherectomy system has two switches: 1) the cutter driver main power switch and 2) the HawkOne catheter thumb switch. The cutter driver main power switch supplies power to the device when turned On. The HawkOne catheter thumb switch activates the drive shaft and engages the cutter when pulled proximally to the On position. With the cutter engaged, the HawkOne catheter is slowly advanced across the lesion, shaving occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the HawkOne catheter thumb switch distally, deactivating the drive shaft and disengaging the cutter. The HawkOne catheter thumb switch is fully advanced distally to the Off position in order to pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

5. Indications for Use

The HawkOne Directional Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

6. Comparison of Technological Characteristics

The proposed HawkOne Directional Atherectomy System is substantially equivalent to the currently marketed TurboHawk Peripheral Plaque Excision Systems (K111723 and K103618). The proposed and predicate devices share the following technological characteristics:

- Intended Use
- Fundamental scientific technology
- Principles of Operation
- Conditions of Use
- Packaging Materials
- Sterilization site, method, parameters, and sterility assurance level

Additionally, the indications for use, labeling, device materials, and manufacturing site and methods are similar between the proposed and marketed devices.

7. Performance Testing Summary

To demonstrate substantial equivalence of the proposed HawkOne Directional Atherectomy System to the predicate device, bench testing was performed.

Using internal Risk Analysis procedures, the following tests were performed:

- Device Inspections
- Urge Force
- Cycle and Life
- Cutter Height
- Tracking Force
- Repeated Cutter Spin Down and Packing

- Shaft Torque Tests
- Carbide Edge Attachment
- DFT Torque and Pressure Tests
- Device Tensile Tests
- Catheter and Cutter Driver Interaction
- Embolization
- Cut Mass Per Pass (Tissue Removal Rate)
- Tissue Removal Cycles
- Package Integrity
- Biocompatibility

The results from these tests demonstrate that the technological characteristics and performance criteria of the HawkOne Directional Atherectomy System are comparable to the predicate device and that the HawkOne Directional Atherectomy System performs in a manner equivalent to the predicate device currently on the market.

8. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, Covidien considers the proposed HawkOne Directional Atherectomy System to be substantially equivalent to the currently marketed TurboHawk Peripheral Plaque Excision Systems (K111723 and K103618).